



Attorney Docket No.: 5739.200-US

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Weibel et al.

Application No.: 09/450,609

Group Art Unit: 1617

Filed: November 30, 1999

Examiner: Kim, J.

For: New Pharmaceutical Composition And The Process For Its Preparation

AMENDMENT AND REMARKS UNDER 1.111

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Office Action issued 22 November 2000, please

Cancel claims 1-5, 8, 10, 14-15, and 17-19 without prejudice or disclaimer, and

Substitute the following amended claims for the pending claims having the same claim numbers:

Sub 91
BT

6. (Amended) A pharmaceutical composition comprising
5-[[4-[3-Methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenyl-
methyl]thiadiazolidine-2,4-dione or a pharmaceutically acceptable salt thereof,
and pharmaceutically acceptable excipients with low water content comprising anhydrous
lactose, microcrystalline cellulose, magnesium stearate, and talc.

Sub 92
B2

9. (Amended Twice) The pharmaceutical composition according to claim 6 wherein the
pharmaceutically acceptable excipients are
between 100 and 400,000 parts by weight of anhydrous lactose,

B2
B2
cont

between 1000 and 10,000 parts by weight of microcrystalline cellulose, and between 10 and 500 parts by weight of magnesium stearate, expressed in parts by weight per 100 parts of 5-[[4-[3-Methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenyl-methyl]thiadiazolidine-2,4-dione, or of one of its pharmaceutically acceptable salts.

B3

16. (Amended Twice) The pharmaceutical composition according to claim 6, further comprising at least one sweetener, flavouring agent, colour or lubricant.

Please add the following new claims:

28. The pharmaceutical composition according to claim 6 in tablet form, wherein the tablet is formed by direct compression.

B4 Sub 3

29. The pharmaceutical composition according to claim 6 consisting of

5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiadiazolidine-2,4-dione or a pharmaceutically acceptable salt thereof	9%
Microcrystalline cellulose	20%
Anhydrous lactose	66%
Magnesium Stearate	0.5%
Talc	4.5%

30. The pharmaceutical composition according to claim 29 in the form of a tablet, a powder or a capsule.

31. The pharmaceutical composition according to claim 30 in tablet form, wherein the tablet is formed by direct compression.
